Stanley Manne
Children's Research Institute™

Informed Consent:
Concepts and Process

Kaleigh Michalko, MS, CIP
Kimberly Rowan

Office of Research Integrity and Compliance

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Ann & Robert H. Lurie
Children's Hospital of Chicago®

Institutional Review Board (IRB)

- Protect participant rights and promote safety in research
- Apply federal regulations and institutional policy
- Help researchers navigate requirements

Overview

Definitions and Concepts

- Purpose of consent
- Consent for various audiences
- Assent
- When consent is required, when it isn't
- Special populations

Development and Process

- Form/script development
- Process considerations
- Documenting consent
- Resources

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Informed Consent:
Definitions and Concepts

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Conceptual Overview

- Ongoing Process
- Respects personal agency
- Protects subjects:
  - Emphasizing voluntary participation
  - Risks and benefits
  - Alternatives
  - Privacy and confidentiality
  - Rights
  - Contact info
- Facilitated by forms/approved text

Types of Consent

- Adult participant
  - Age 18+
  - Required when minors turn 18 during ongoing participation
- Legally Authorized Representative
  - On behalf of an adult who cannot be consulted
- Parental/guardian permission
  - On behalf of a minor

What is Assent?

- Child's affirmative agreement to participate in research
- Tailored to age, maturity, psychological state
- IRB may waive assent requirement due to limited capacity or other special cases

When is Consent Needed?

- If in doubt, plan for consent
- Parental permission typically required when minors involved
- Depends on:
  - Risk level
  - Approval category
- Quality Improvement:
  - Consent not required if activity is NOT "human subjects research"

When is Assent Needed?

- When children can be consulted about their participation
- Lurie policy: signed assent for ages 12-17
  - Collect assent upon turning 12 if long-term study
- No specific age of assent

When is the consent requirement waived?

- Parental: when not a reasonable requirement to protect participants (e.g. abuse)
- Adult:
  - No more than "minimal risk"
  - Research could not be conducted without waiver
  - Would not adversely affect rights
  - Subjects will be given notice after the research is conducted, when appropriate

When is the assent requirement waived?

- Minors cannot be consulted due to limited capacity to agree (e.g. infants, sedation)
- May also be waived for similar reasons as adult consent (low risk, could not be conducted without a waiver)

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Informed Consent Form Development

- Readability – 6-8th grade reading level
- Must include all elements of consent:
  - Statement that the study involves research
  - Purpose of the research
  - Description of all procedures
  - Risks/discomfort & benefits
  - Disclosure of alternative treatment or options
  - Confidentiality
  - Compensation
  - Injury language

ICF Development Continued

- HIPAA Privacy Rule elements for the use and disclosure of PHI for research purposes:

  - Which PHI to be used or disclosed
  - Identify Individuals/agencies authorized to make the requested use or disclosure
  - Individuals/agencies who may use the PHI
  - Purpose of the requested use or disclosure
  - Expiration date/expiration event that relates to the purpose of the use or disclosure ("end of research study" or "indefinitely" is permissible)
  - Statement to indicate an individual's right to revoke their authorization in writing and the exceptions to the right to revoke
  - Statement with the consequences of refusing to sign the authorization
  - Potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule.

ICF Development Continued

- Use plain language
- Define/explain medical terms
- Use the active voice:
  - "We will ask you questions about your health" (active)
  - "You will be asked questions about your health" (passive)
- Break up dense-looking pages and paragraphs
- Read aloud
- Ask a colleague to proofread and provide feedback
- Use short and simple words
  - Example: "administer the drug" vs. "give the drug" or "utilize" vs. "use"

Parent Permission for a Child to Participate in a Research Study

Study Name: *Insert Title of study*
If applicable: **Sponsored by:** *Insert Sponsor Information*
Name of Researcher (referred to as the study doctor): *Insert Principal Investigator's Name*

This consent form describes a research study for which your child might qualify at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") and *(insert sites as applicable)* Northwestern University (NU),Northwestern Memorial HealthCare (NMHC) and Shirley Ryan Ability Lab. Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care.

What are the purpose and goals of this study?

Describe the main purpose of the study in simple terms, the population being studied, and the number of participants to be enrolled at all sites.

If I agree to have my child take part in this study, what would my child and I need to do?

- *Describe all research related exams, tests, and procedures that are not done as standard care or that will be done more frequently (e.g. extra scans, blood draws, sample collections, etc.). Identify any experimental procedures. It is only necessary to describe the research procedures once. It is recommended to follow this information with a simple table outlining what happens at each study visit and the duration of the visit.*
- *Provide a clear delineation between standard of care and research procedures.*
- *Optional study procedures should not be included here.*
- *When samples are collected, state the volume or amount of each sample, the total volume/amount, and site of sample removal.*

Informed Consent Process Do's

- Only study personnel knowledgeable in all elements of the study may obtain consent
- Informed consent must:
  - Start with concise presentation of the key information likely to assist participant understanding
  - Adequate location/timing
  - No exculpatory language
- Enough information to make an informed decision about participation
- Adequate opportunity to discuss
- Information presented in sufficient detail to facilitate understanding
- Sign and date form
- Give each participant a signed and dated copy of the consent form

Informed Consent Process Don'ts

- Do not rush the process
- Don't leave any blank lines
- Do not use your own templates
- Do not use expired forms
- Do not forget to have impartial witness
- Do not forget documentation of consent for each participant

Informed Consent Process Continued

- To ensure comprehension:
  - "teach back" by asking participant questions
- Consider the process
- Know your protocol
- Know your audience
- Training is vital

Documentation of Consent

- Documentation of Consent must contain:
  - verification that the study was explained to the subject, parent/guardian, and/or LAR
  - enough time was given for them to review the consent
  - all questions were answered
  - consent/assent was obtained prior to study procedures
  - any other specifics of the consent process (i.e. if an interpreter and short form were used, if consent was obtained over the phone and why, etc.)

Forms

Research Innovation→ Toolkit →IRB Website→ IRB Resources

- Informed Consent Form Templates
- Biomedical Studies
  - *Greater than Minimal Risk Biomedical Studies*
  - *Minimal Risk Biomedical Studies*
- Social Behavioral Studies
  - *Minimal Risk Social/Behavioral Studies*

- Parent Permission Template (version 8/22/19) for enrolling children under 18 years of age
- Adult Consent Template (version 8/22/19) for enrolling participants ages 18 years and up

- Adolescent Assent Template for All Study Types
  - Adolescent Assent Template (version 8/22/19) for enrolling children ages 12-17 years on any type of study

Forms continued

Research Innovation→ Toolkit →IRB Website→ IRB Resources

- Templates for Verbal Consent and Surveys
  - Information Sheet Template
    - for enrolling participants with a Waiver of Signed Consent
  - Anonymous Survey Template
    - for enrolling participants on an anonymous survey study
  - Identifiable Survey Template
    - for enrolling participants on an identifiable survey study

Resources

- Researcher Toolkit → IRB Website
  - Suggestions and Guidance for Writing Consent and Assent Forms
  - IRB Library of Procedures, Terms and Risks
  - Post Approval Monitoring Informed Consent Checklist
- Office of Research Integrity & Compliance
- CRPedia
- Mock process
- PRISM Readability Toolkit
- Evaluation Core

Key Takeaways

- Consent is a process intended to respect a person's right to make decisions about their time, body, and information
- Participation in research is always voluntary
- Children's capacity to agree must be respected whenever possible
- Reasonable accommodations exist for special circumstances or populations when traditional consent may not be possible
- Consent should be informative, easy to understand, and free of pressure
- Documentation protects rights and ensures a thorough process
- IRB staff are available for guidance

Contact Us:

- General IRB inquiries: 312-503-7110 or IRB@luriechildrens.org

- IRB Coordinators (by PI Last Names):
  - A-B: Kristen Brown 312-503-7681
  - C-F: Jillian Anderson 312-503-7663
  - G-L: Madeleine Kaczmarowski 312-503-7049
  - M-Q: Kimberly Rowan 312-503-7048
  - R-Z: Jennie Thai 312-503-7027
  - Single IRB: Kaleigh Michalko 312-503-7058

- Stop by the ORIC satellite office for study/submission-specific help when needed (19-376) every other Monday and Tuesday from 8am-12pm.

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Questions?

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